

Appl. No. : 09/737,165
Filed : December 14, 2000

REMARKS

By way of summary, Claims 1–10, 21, 29–33, 65–71, and 74 are now pending in this application. The Office Action dated April 29, 2005, rejected Claims 1–10, 21, 29–33, and 65–71 as being anticipated under 35 U.S.C. § 102(e). Claims 29, 60, 65, and 68 are amended in this response, and Claim 74 is added. By way of the foregoing amendments and following comments, it is believed that Claims 1–10, 21, 29–33, 65–71, and 74 are patentably distinguished over the cited reference, and Applicants respectfully request allowance of the pending claims.

ALLOWED CLAIMS

Applicants would like to thank the Examiner for the indication of allowance of Claims 60–64 in the Office Action dated April 29, 2005.

CLAIM REJECTIONS UNDER 35 U.S.C. § 102(e)

The Office Action rejected the pending claims under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,156,046, issued to Passafaro et al. Applicants respectfully traverse this rejection because the Passafaro patent fails to identically teach every element of the rejected claims. See M.P.E.P § 2131 (stating that in order to anticipate a claim, a prior art reference must identically teach every element of the claim).

The Passafaro Patent

Passafaro discloses an apparatus and methods for guided atherectomy. Col. 1, lines 8–9. The system includes a catheter, a torque member, a cutting mechanism at the distal end of the torque member, and a guidewire to control the movement of the cutting mechanism. Col. 1, lines 15–20. After cutting, the system removes occluding material through use of a “conveyer mechanism.” Col. 3, lines 40–52. A preferred embodiment of such a conveyer mechanism is the use of an outer coil attached to the torque member, in close proximity to the wall of catheter, to form a helical annulus for aspiration. Col. 10, lines 3–24. Rotation of the torque member is accomplished using a motor controlled via a “control switch.” Col. 13, lines 66–67 and Col. 14, line 1.

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Independent Claim 1

The Office Action states the “Passafaro et al device is clearly capable of having a sensor in electrical communication with an indicator (located within control (42)) for indicating resistance to rotation of either the rotatable element or rotatable cutter.” Office Action dated April 12, 2005, page 3. Claim 1 recites, among other things, “a sensor on the device in electrical communication with an indicator, for indicating resistance to rotation of either the rotatable element or rotatable cutter.” The Office Action’s conclusory remarks that the device is *clearly capable* of having the sensor-indicator system disclosed in Claim 1 relies on no specific teaching or suggestion in Passafaro and fails to consider the significant and innovative reconstruction that would be required to modify the Passafaro device in order to meet the limitations of Claim 1. The Passafaro patent does not teach of any sensor or indicator in general, and certainly not one to indicate resistance to the rotation of either the rotatable element or rotatable cutter. The only mention of the motor control is via the use of wire leads connecting the motor to a control switch 174 (Passafaro, at Col. 13, lines 66–67 and Col. 14, line 1), which from Figure 7 appears to be for manual operation.

Therefore, it is respectfully submitted that Passafaro does not teach or suggest all the limitations of Claim 1, and withdrawal of the rejection under 35 U.S.C. § 102(e) is respectfully requested.

Independent Claim 21

The Office Action also states, regarding a limitation of Claim 21, “Passafaro et al discloses in figures 1, 3, 7, and 10, . . . an aspiration lumen (50) . . . wherein the cross-sectional area of the aspiration lumen (50) is being at least about 35% of the cross-sectional area of the tubular body (32).” Office Action, page 3. However, there is no teaching in the Passafaro patent for an aspiration lumen sized to be “at least 35% of the cross-sectional area of the tubular body.” While the figures of Passafaro include embodiments of an aspiration lumen, “when the reference does not disclose that the drawings are to scale and is silent as to dimensions, arguments based on measurement of the drawing features are of little value.” See M.P.E.P. § 2125 (citing *Hockerson-Halberstadt, Inc. v. Avia Group Int’l*, 222 F.3d 951, 956, 55 USPQ2d 1487, 1491 (Fed. Cir. 2000)).

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Passafaro never discloses that the drawings are to scale, and the reference fails to provide a basis for anticipating the “at least 35%” limitation. Nowhere in the text does Passafaro disclose such a limitation. Therefore, it is respectfully submitted that Passafaro does not teach or suggest all the limitations of Claim 21, and withdrawal of the rejection under 35 U.S.C. § 102(e) is respectfully requested.

Independent Claim 29

The Office Action also states, regarding Claim 29, “Passafaro et al discloses in figures 1, 3, 7, and 10 . . . an aspiration lumen (50) extending through said tubular body (32).” Office Action, page 2. However, amended Claim 29 further defines the rotatable cutter as being disposed within the tubular body. Passafaro does not teach or suggest a rotatable cutter that is disposed within the tubular body. Additionally, Passafaro discloses a snap ring arrangement on the distal end of the tube that would actually prevent the rotatable cutter from being drawn into the tubular body. Col. 13, lines 31–33.

It is respectfully submitted that Passafaro does not teach or suggest all of the limitations of Claim 29, and withdrawal of the rejection under 35 U.S.C. § 102(e) is respectfully requested.

Independent Claim 65

The Office Action also states, “Passafaro et al discloses in figures 1, 3, 7, and 10 . . . a . . . hub disposed on the proximal end of tubular body.” Office Action, page 2. Amended Claim 65 recites, in part, a “control including a connection hub, the connecting hub coupling the tubular body to the control such that the tubular body may rotate relative to the control during operation.” Passafaro, however, fails to teach such a hub that permits rotation relative to the control and that is disposed on the proximal end of the tubular body. Passafaro teaches that a “conventional male-female luer fitting 163 is also provided in the rear portion 154 to connect the proximal connector assembly 40 to a front portion 165 of the hand-held device.” Col. 13, lines 59–62. Accordingly, Passafaro only contemplates a conventional male-female luer fitting; the reference does not contemplate a hub for “coupling the tubular body to the control such that the tubular body may rotate relative to the control.”

Therefore, it is respectfully submitted that Passafaro does not teach or suggest all the limitations of Claim 65, and withdrawal of the rejection under 35 U.S.C. § 102(e) is respectfully requested.

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Independent Claim 68

The Office Action rejects independent Claim 68 as being anticipated under 35 U.S.C. § 102(e) by the Passafaro patent. However, amended Claim 68 recites, among other things, a “cutter capable of axial displacement relative to the control during operation.” Passafaro discloses a system that does not allow for axial displacement. Instead, Passafaro discloses a bearing assembly that is configured to “allow rotation of the removal mechanism and the torque member while preventing axial movement of the torque member and removal mechanism relative to the catheter.” Col. 3, lines 36–39. Inasmuch as the catheter is connected to the hand-held device via a male-female luer, and is therefore not axially movable with respect to hand-held device, it follows that the torque member will also not have axial movement relative to the hand-held device. Thus, Passafaro teaches a device in which the cutter is not capable of axial displacement relative to the hand-held device, and the reference does not anticipate Claim 68 under 35 U.S.C. § 102(e).

Therefore, it is respectfully submitted that Passafaro does not teach or suggest all the limitations of Claim 68, and withdrawal of the rejection under 35 U.S.C. § 102(e) is respectfully requested.

Dependent Claims 2–10, 30–33, 66–67, 69–71, and 74

Claims 2–10, 30–33, 66–67, 69–71, and 74 which depend from Claims 1, 29, 65, and 68, are believed to be patentable for the same reasons articulated above with respect to Claims 1, 29, 65, and 68, and because of the additional unique features recited therein. Accordingly, it is respectfully submitted that Passafaro does not teach or suggest all the limitations of these claims or the independent claims from which these claims depend, and withdrawal of the rejection under 35 U.S.C. § 102(e) is respectfully requested.

CONCLUSION

In view of the foregoing, the present application is believed to be in condition for allowance, and such allowance is respectfully requested. If further issues remain to be resolved, the Applicants’ undersigned attorney of record hereby formally requests a telephone interview with the Examiner. The Applicants’ attorney can be reached at (949) 760-0404.

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In addition, please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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